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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/992,738 | 11/14/2001 | Hongjiang Wu | ISPH-0614 | 8931 |

7590

11/10/2003

Licata & Tyrrell P.C.
66 East Main Street
Marlton, NJ 08053

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| EXAMINER |
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PATTERSON, CHARLES L JR

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/992,738 | WU ET AL. | |
| | Examiner | Art Unit | |
| | Charles L. Patterson, Jr. | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003 and 22 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 20-42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the sequence in Figure 1A is not contained in the sequence listings. Also, the figure is not labeled as to SEQ ID NO, as required by the instant rules. Preferably this should be done in the Brief Description of the drawings on page 7. The identity of the sequence in Figure 1 is not at all clear from the specification. For example on page 4, first paragraph, lines 8-12, it appears that the sequence is that of *E. coli* H1 enzyme. From the second paragraph of that page, line 22, it appears it is the human H1 enzyme. Because the application could be examined without this disclosure this has been done, however this sequence disclosure must be accomplished before the issuance of a patent based on this application.

It is not clear what SEQ ID NO:1 and 2 are because they are not identified.

Applicant's election with traverse of Group I, claims 1-19, in the paper filed 9/22/03 is acknowledged. The traversal is on the ground(s) that the inventions are not distinct as defined in the MPEP and that it would not be a serious burden upon the examiner to examine all of the groups. This is not found persuasive because in MPEP § 802.01 the meaning of "independent" and "distinct" is discussed, along with a discussion of the legislative history of these terms in patent law. It is concluded in MPEP § 803 that restriction is proper when the inventions "are either independent (MPEP § 806.04-§ 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i))" (emphasis added). Furthermore, it is maintained that for the examiner to examine all of the

Art Unit: 1652

groups would be a serious burden because, as stated in the restriction, the enzymes are different and different things are involved, e.g. whether a 35 USC § 101 rejection should be done on Group II. The methods of Groups III-IV involve different things than the enzyme of Group I and furthermore, the enzyme of Group I could be used for a materially different process such as cleaving a RNA/DNA complex not involved with the methods of Groups III-IV.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 9/22/03.

The disclosure is objected to because of the following informalities:

On page 7, the description of Figure 1 states that the substitution "E186Q". This is not understood because the sequence shown in the instant figure has I at residue 186. It is pointed out that the figure is extremely confusing because the numbering of residues 50, 200 and 250 are apparently incorrect. The examiner counted from the beginning to obtain the residue numbers. What does the underlined sequence indicate? It almost indicates Region II. however Region II is apparently from residues 74-135 and the underlined region is 74-136.

Appropriate correction is required.

Claims 4, 5, 7, 11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1652

Claims 4 and 5 are indefinite in the recitation of the residue positions 226 and 227 without a recitation of the SEQ ID NO that they correspond to.

Claims 7 and 11 are indefinite in the recitation of the parentheses. Parentheses should generally be avoided in patent claims. It is not clear whether the parenthetical expression is meant to be a limitation of the claims or merely illustrative.

Claim 17 is confusing and indefinite in the recitation of "the cleavage pattern obtained is broader than that of a wild type human RNase H1". What is meant by "broader". This term does not appear to be defined in the specification and is unclear to one reading the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10, 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification teaches how to make a human H1 enzyme retaining activity by changing Lys to Ala at both positions 226 and 227, deleting all of Region I or II or deleting all of Regions I and II. It does not teach one of ordinary skill in the art how to make an enzyme retaining activity by the methods of the instant claims. Exactly what will occur when a point mutation and/or deletion is made to an enzyme is not known until the change is made

Art Unit: 1652

and the resulting mutant enzyme assayed. One might predict what the effect will be but that is just that, a prediction.


Claims 11-13 are allowed.

No art rejection is being made. The examiner could find nothing in the prior art teaching what effect particular point mutations and/or deletions would have on the activity of human RNase H1 enzyme.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-305-74014242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
November 5, 2003